



August 23, 1999

8732 '99 AUG 30 09:55

Dockets Management Branch (HFA-305)
Food and Drug Administration
\$630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 99N-1737: Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions

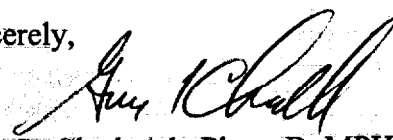
Dear Sirs;

On behalf of the Applied Research Ethics National Association (ARENA) we are writing regarding the above referenced public notice. ARENA is dedicated to promoting the ethical conduct of research. ARENA is a membership organization **with nearly 1,000 members**, including Institutional Review Board (IRB) chairs and **administrators**. ARENA promotes individual professional development opportunities and **public** policy awareness for those involved in the day-to-day application of ethical principles, government regulations, and other policies regarding research.

We believe that public availability of information on investigational device trials is an important issue that will greatly impact the public, research institutions, and Institutional Review Boards (IRBs). **Unfortunately, we believe that the** agency has not provided sufficient time for public response to the federal register notice. Therefore, we request a 60 day extension to the public comment period in order to provide comments on this important issue.

Thank you for consideration, of our request.

Sincerely,


Gary L. Chadwick, PharmD, MPH
President

cc: Ada Sue Selwitz, ARENA Public Policy Committee Co-Chair
ARENA Public Policy Committee

Steven Peckman
Public Policy Sub-Committee Chair

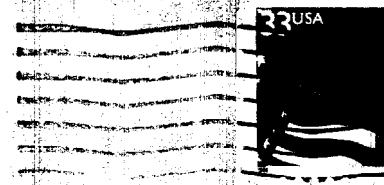
Joan Rachlin
PRIM&R Executive Director

99N-1737

EXT 2



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